

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

FENNEC PHARMACEUTICALS INC.,

Plaintiff,

v.

**CIPLA LIMITED AND CIPLA USA,
INC.,**

Defendants.

Civil Action No. 23-123 (JKS)(MAH)

OPINION

I. INTRODUCTION

This matter comes before the Court by way of Fennec Pharmaceuticals Inc’s (“Fennec”) motion to amend the Joint Claim Construction and Prehearing Statement (“JCCS”). *See generally* Mot. to Am. JCCS, D.E. 100. Fennec seeks to amend the JCCS to remove all constructions for U.S. Patent Nos. 11,291,728 (the “’728 patent”) and 11,510,984, (the “’984 patent”). Fennec also seeks to amend its proposed constructions for two disputed claims terms in the remaining patent, U.S. Patent No. 11,617,793 (the “’793 patent”). Mem. in Supp., D.E. 100-1, at 1. Defendants Cipla Limited (“Cipla Ltd.”) and Cipla USA, Inc. (“Cipla USA,” collectively “Cipla”) oppose Fennec’s motion. Mem. in Opp., D.E. 101. Pursuant to Federal Rule of Civil Procedure 78 and Local Rule 78.1, the Court decides this motion without oral argument. For the reasons set forth below, the Court grants Fennec’s motion to amend the JCCS.

II. BACKGROUND

This action arises under 35 U.S.C. § 100. Fennec brought the instant suit for patent infringement under the Hatch-Waxman Act against Cipla, through a Complaint filed on January 10, 2023. Compl., D.E. 1. Fennec asserts ownership of U.S. Patent Nos. 11,291,728 (the “’728

patent”) and 11,510,984, (the “’984 patent”). *Id.* Fennec is also the exclusive licensee of 10,596,190 (the “’190 patent”). *Id.* Fennec alleges that Cipla seeks to market an allegedly infringing version of PEDMARK,[®] a sodium thiosulfate formulation covered by these patents. *See generally* Compl., D.E. 1. PEDMARK[®] is a sodium thiosulfate injection, which the FDA approved on September 20, 2022 to reduce the risk of ototoxicity associated with cisplatin in pediatric patients one month of age and older with localized, non-metastatic solid tumors. *Id.* ¶¶ 1, 7. The PEDMARK[®] patents are listed in the FDA’s *Approved Drug Products with Therapeutic Equivalence Evaluations* (known as the “Orange Book”). *Id.* ¶¶ 11-12.

The instant litigation arises because Cipla prepared and submitted an Abbreviated New Drug Application No. 218028 (“Cipla ADNA”), pursuant to 21 U.S.C. § 355(j), that seeks approval to manufacture, use, and/or sell sodium thiosulfate to reduce the risk of ototoxicity induced by cisplatin chemotherapy. *Id.* ¶ 13. Cipla also filed a Paragraph IV Certification contending that each of the PEDMARK[®] Orange Book listed patents is invalid and/or Cipla’s ANDA product would not infringe Fennec’s PEDMARK.[®] *Id.* ¶ 16. Fennec alleges that Cipla infringed its patents by filing the Cipla ANDA and Paragraph IV Certification. *Id.* ¶¶ 20-21.

On April 20, 2023, Fennec amended the Complaint to remove claims for infringement of the ’190 patent.¹ Am. Compl., D.E. 32. On June 14, 2023, the Court held a scheduling conference with the parties and entered a Pretrial Scheduling Order (“PTSO”) on July 5, 2023. PTSO, D.E. 52. The PTSO designated October 29, 2024, as the deadline for parties to amend or supplement the pleadings. *Id.* at 3. On July 27, 2023, Fennec filed a Second Amended

¹ Fennec also removed Oregon Health and Science University, which had been named in the Complaint, as a named Plaintiff. *See, generally*, Am. Compl., D.E. 32.

Complaint, adding claims for infringement of the then-newly issued '793. Sec. Am. Compl., D.E. 54.

The parties were to file their JCCS in accordance with Local Patent Rule 4.3 by March 21, 2024. Joint Stipulation and Order Regarding Modification of Scheduling Order, D.E. 91. On March 21, 2024, the parties jointly filed the JCCS. JCCS, D.E. 92. On April 21, 2024, Fennec notified Cipla that “[i]n the course of developing Fennec’s claim construction briefing, we have come to the conclusion that the asserted patents’ lexicography should control for the constructions of the aqueous anhydrous sodium thiosulfate and sodium thiosulfate terms in the three asserted patents.” Certification of Eric Alan Stone (“Stone Cert.”), Ex. 3, Email Exchange Between Counsel, Apr. 21, 2024, D.E. 100-2, at 101. On April 23, 2024, Cipla responded that because the newly proposed constructions for the sodium thiosulfate terms were markedly different and were more than minor revisions, Cipla wished to meet and confer. *Id.* at 98. The parties met and conferred on a couple of occasions concerning Fennec’s proposed revisions to the JCCS and the sodium thiosulfate terms. *Id.* at 93-98. Despite the parties’ attempts, they were unable to informally resolve the dispute. Accordingly, on May 6, 2024, Fennec filed a motion to amend the JCCS. Mot to Am. JCCS, D.E. 100, at 1. On May 14, 2024, Cipla opposed Fennec’s motion to amend. Def. Brief in Opp’n., D.E. 101. On May 21, 2024, Fennec filed a reply brief in further support of its motion to amend the JCCS. Reply, D.E. 102.

On June 13, 2024, and while the instant motion was pending, Fennec filed a motion for leave to file a Third Amended Complaint to add claims for infringement of the newly issued and related U.S. Patent No. 11,964,018 (the “’018 patent”), and to remove claims for infringement of the ’728 and ’984 patents. Mem. in Supp. of Mot. to Amd., D.E. 103-1, at 1. Cipla ultimately decided not to oppose Fennec’s motion to file a Third Amended Complaint, after Fennec

indicated that filing the Third Amended Complaint to add the '018 patent would not extend the case schedule or cause additional delay.² Letter, July 22, 2024, D.E. 106. On July 30, 2024, the parties filed a Joint Stipulation with an accompanying Court Order setting forth additional deadlines regarding the '018 patent. Letter with Stipulation, D.E. 108; Joint Stipulation and Order, D.E. 109. The Third Amended Complaint is now the operative complaint in this matter. Third Am. Compl., D.E. 122.

III. DISCUSSION

A. Legal Standard

Local Patent Rule 4.3 governs the filing of the parties' Joint Claim Construction and Prehearing Statement. Under the Rule, the parties are required to file the JCCS within thirty days of their exchange of preliminary claim constructions required by Rule 4.2(a). L. Pat. R. 4.3. Local Patent Rule 3.7 controls any amendment to the JCCS and prescribes that "[a]mendment of any contentions, disclosures, or other documents required to be filed or exchanged pursuant to these Local Patent Rules may be made only by order of the Court upon a timely application and showing of good cause." L. Pat. R. 3.7. The rule sets out a non-exhaustive list of circumstances that may support a showing of good cause, absent undue prejudice to the opposing party. *Id.* Accordingly, a court should permit an amendment where there is a timely application, a showing of good cause, and no undue prejudice to the adverse party. *AstraZeneca AB v. Hanmi, USA, Inc.*, No. 11-760, 2013 WL 264609, at *1 (D.N.J. Jan. 23, 2013).

A showing of good cause considers first whether the moving party was diligent, and then whether amendment would prejudice the nonmoving party. *Eagle View Techs., Inc. v. Xactware*

² The parties also agreed that the '728 and '984 patents should be removed from this litigation. Joint Stipulation and Order, D.E. 109.

Solutions, Inc. No. 15-7025, 2017 WL 5886004, at *9 (D.N.J. Nov. 29, 2017). To support a finding of diligence, courts consider whether the moving party acted diligently to discover that amendment was appropriate, and whether the moving party acted timely to amend. *Id.* at *3. The moving party bears the burden of establishing diligence. Additional considerations include: (1) the reason for the delay; (2) the importance of what is to be excluded; (3) the danger of prejudice; and (4) the potential impact of delay on judicial proceedings and availability of a continuance. *Id.* In determining what constitutes prejudice, the court should consider whether amendment would: (1) require the opposing party to expend significant resources to conduct discovery; (2) significantly delay resolution; or (3) prevent the plaintiff from bringing a timely action in another jurisdiction. *See Cochlear Ltd. v. Oticon Med. AB*, No. 18-6684, 2019 WL 3429610, at *7 (finding that amendment of infringement contentions would not prejudice defendant because granting the amendment would not significantly delay litigation).

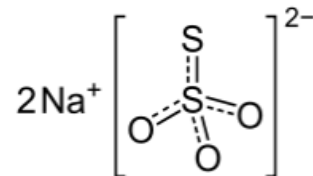
“The Local Patent Rules exist to further the goal of full, timely discovery and provide all parties with adequate notice and information with which to litigate their case.” *Razor USA LLC v. DGL Grp., Ltd.*, No. 19-12939, 2020 WL 3605296, at *2 (D.N.J. July 2, 2020) (quoting *King Pharms., Inc. v. Sandoz Inc.*, No. 08-5974, 2010 WL 2015258, at *4 (D.N.J. May 20, 2010)). “The Patent Rules ‘are designed to require the parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed.’” *Id.* (quoting *Celgene Corp. v. Natco Pharma Ltd.*, No. 10-5197, 2015 WL 4138982, at *4 (D.N.J. July 9, 2015)). That said, “a modest degree of flexibility exists, at least near the outset,” with respect to the parties’ respective theories of the case. *AstraZeneca v. Dr. Reddy’s Laboratories Inc.*, No. 11-2317, 2013 WL 1145359, at *2 (D.N.J. Mar. 18, 2013) (internal quotation marks omitted); *see also O2 Micro Int’l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1366 (Fed. Cir. 2006) (“If a local patent

rule required the final identification of infringement and invalidity contentions to occur at the outset of the case, shortly after the pleadings were filed and well before the end of discovery, it might well conflict with the spirit, if not the letter, of the notice pleading and broad discovery regime created by the Federal Rules.”).

B. Whether Fennec Has Established Good Cause to Amend

Fennec filed the instant motion to amend the JCCS to: (1) remove all constructions for the ’728 and ’984 patents;³ and (2) amend its proposed constructions for two terms in the ’793 patent to mirror the definitions of these terms in the patent itself. The terms in dispute include “sodium thiosulfate” and “sodium thiosulfate at a concentration of about 0.5 M.” Letter in Supp., D.E. 100-1, at 3. In the JCCS the parties filed on March 21, 2024, Fennec proposed a construction for “sodium thiosulfate” in Claim 1 of the ’793 patent as the following:

An inorganic salt with a molecular formula of $\text{Na}_2\text{S}_2\text{O}_3$, a structural formula of



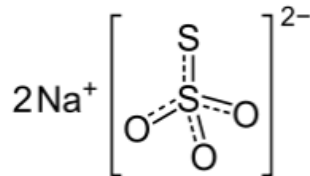
and a molecular weight of 158.11 g/mol where the term does not imply any particular physical state or imply that the compound is in a solid state with a particular crystalline structure, *e.g.*, a solvate or non-solvate form.

Ex. 2, Redlined Version of the JCCS, D.E. 100-2, at 82-84. Fennec now seeks to amend its construction of “sodium thiosulfate” to: “A water-soluble thiol compound with the formula of $\text{Na}_2\text{S}_2\text{O}_3$.” *Id.*

³ Cipla does not oppose Fennec’s request to remove the ’728 and ’984 patents from the litigation. Mem. in Supp., D.E. 103-1, at 9. Therefore, this Opinion analyzes only whether Fennec should be permitted to amend the JCCS.

Fennec also seeks to amend its construction of “sodium thiosulfate at a concentration of 0.5 M” in Claim 1 of the ’793 patent, for which it had proposed a construction of:

Plain and ordinary meaning which is: “a liquid formulation comprising sodium thiosulfate, *i.e.*, an inorganic salt with a molecular formula of $\text{Na}_2\text{S}_2\text{O}_3$, a structural formula of



and a molecular weight of 158.11 g/mol, where the sodium thiosulfate concentration in the formulation is 0.5 M or an integer or fractional component that is within a variation of up to $\pm 10\%$ of 0.5 M, *i.e.* sodium thiosulfate is at a concentration between 0.45 M and 0.55 M.”

Id. at 84-86. Plaintiff proposed the following revised construction for “sodium thiosulfate at a concentration of 0.5 M”:

A liquid formulation comprising sodium thiosulfate, where the sodium thiosulfate concentration in the formulation is 0.5 M or an integer or fractional component that is within a variation of up to $\pm 10\%$ of 0.5M *i.e.*, sodium thiosulfate is at a concentration between 0.45 and 0.55 M.

Id. This “new proposed construction simply replaces the longer definition of ‘sodium thiosulfate’ with the term itself, as that term is being construed separately.” Letter in Supp., D.E. 100-1, at 4.

i. Fennec’s Position

Fennec argues it should be permitted to amend the JCCS because its application is timely, there is good cause, and amendment would not prejudice Cipla. Letter in Supp., D.E. 100-1, at 5. Fennec contends that the amendment is timely because the claim construction hearing is not yet scheduled, parties have not yet filed their opening *Markman* briefs, fact discovery will not close until November 2024, and expert discovery is not expected to close until April of 2025. *Id.* at 5. Furthermore, Fennec argues there is good cause for amendment because it notified Cipla as

soon as it realized that the original constructions for “sodium thiosulfate” differed from the express definition of the term set forth in the ’793 patent. *Id.* According to Fennec, Cipla will not suffer prejudice because amendment of the JCCS will not cause Cipla to expend additional resources, and Cipla will have an opportunity to challenge Fennec’s proposed constructions during the *Markman* proceedings. *Id.* at 6.

ii. Cipla’s Position

Cipla argues that Fennec’s motion to amend the JCCS should be denied because Fennec failed to demonstrate good cause and amendment would prejudice Cipla. Def. Brief in Opp’n., D.E. 101, at 5-8. Cipla asserts that Fennec was not diligent in seeking to amend the JCCS. *Id.* at 6. Fennec’s proposed constructions were submitted three days before the deadline to file opening *Markman* briefs, and almost eight weeks after the parties served their preliminary claim constructions. *Id.* Cipla argues that amendment would be prejudicial because it would materially change the claim constructions and require Cipla to expend additional resources to address the now-broader claim constructions. *Id.* at 7. Moreover, Cipla argues that it is entitled to fees incurred because of Fennec’s delay pursuant to Federal Rule of Civil Procedure 16(f). *Id.* at 8. Specifically, Cipla maintains that it will incur substantial attorney’s fees for the additional *Markman* briefing required. *Id.* at 9.

iii. Fennec’s Reply

Fennec responds that its proposed amendment is timely because Fennec filed it within seven weeks of the filing of the JCCS. Reply, D.E. 102, at 1. Fennec points out that any delay in filing the motion was due to the parties’ various meet and confer efforts, and Cipla’s refusal to allow Fennec to amend without the necessity of motion practice. *Id.* at 1-4. Fennec also asserts that the prospect of Cipla having to respond to the new construction is not, itself, unduly

prejudicial. *Id.* at 4-6. Indeed, Fennec argues, the parties have not yet filed *Markman* briefs. *Id.* at 5. Finally, Fennec maintains that Cipla's request for fees should be denied because Cipla has not demonstrated that Fennec violated any court order, a necessary component for sanctions under Rule 16(f). *Id.* at 6-8.

iv. Analysis

a. Timeliness

First, the concludes that Fennec's motion to amend the JCCS to change its construction for sodium thiosulfate is timely. The parties filed the JCCS on March 21, 2024, and Fennec first reached out to Cipla on April 21, 2024. In that communication, Fennec informed Cipla that in drafting its *Markman* brief, Fennec determined that it would be necessary to amend its construction for sodium thiosulfate to bring the construction in line with the patents' own lexicography. The April 21st communication is approximately one month between when the parties filed the JCCS, and when Fennec discovered that it would be necessary to amend its portion of the JCCS. The parties immediately began meeting and conferring in an attempt to informally resolve Fennec's request to amend, including on April 23, 2024 and April 29, 2024. During this time, the parties also presented two stipulations and proposed orders to the Court, to extend the deadlines for *Markman* briefing and set a date by which Fennec would be required to move to amend the JCCS if the parties' informal efforts failed. The Court granted both proposals. Stipulation and Order, D.E. 97; Joint Stipulation and Order, D.E. 99. After the parties reached an impasse, Plaintiff filed the instant motion on May 6, 2024, in accordance with their stipulation. This all occurred within a seven-week period, between March 21, 2024, when the parties filed the JCCS, and May 6, 2024, when Fennec filed the instant motion. Because Fennec notified Cipla immediately after discovering it was necessary to amend the JCCS, and

immediately began meeting and conferring with Cipla to try to informally resolve Fennec's request to amend, and then moved to amend as soon as it became apparent that the parties had reached an impasse, Fennec has demonstrated diligence. The Court cannot find that this motion is untimely or that Fennec delayed in seeking the amendment. *See Abraxis BioScience, LLC v. Actavis, LLC*, No. 16-1925, 2017 WL 2079647, at *4 (D.N.J. May 15, 2017) (finding defendant's motion to amend its invalidity contentions timely where it only took four months "to review . . . response, investigate, prepare and served amended contentions"); *see also Janssen Pharmaceuticals, Inc. v. Sandoz, Inc.*, No. 11-7247, 2013 WL 7901841, at *7 (D.N.J. May 22, 2013) (finding defendant's proposed amendment to its invalidity contentions timely where only three months passed between plaintiff's addition of a new claim and defendant's motion).

b. Good Cause

Next, the Court considers whether Fennec has established good cause for the amendment. Fennec asserts that in drafting its opening *Markman* brief, it discovered that "some of the constructions [it] had placed in the JCCS were not framed using the language of explicit definitions set out in the specification." Letter in Supp., D.E. 100-1, at 2. Fennec maintains because Federal Circuit precedent instructs that "the inventor's lexicography governs[.]" amendment of those constructions is necessary. *Id.* (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1316 (Fed. Cir. 2005)). The terms in dispute include "sodium thiosulfate" and "sodium thiosulfate at a concentration of about 0.5 M." *Id.* at 3. Fennec now seeks to amend its construction of "sodium thiosulfate" in Claim 1 of the '793 to: "A water-soluble thiol compound with the formula of $\text{Na}_2\text{S}_2\text{O}_3$." Stone Cert., Ex. 2, Redlined Version of the JCCS, D.E. 100-2, at 82-84. This is the definition for sodium thiosulfate as set forth in the patent itself. Stone Cert., Ex. 1, Amended JCCS, Ex. 1, '793 Patent, Column 13, Lines 66-67, D.E. 100-2, at 33. With

respect to the second construction that Fennec seeks to amend, this “new proposed construction simply replaces the longer definition of ‘sodium thiosulfate’ with the term itself, as that term is being construed separately.” Letter in Supp., D.E. 100-1, at 4.

Fennec contends that its initial proposed constructions are not inconsistent with the constructions it proposes now, as those were the plain and ordinary meaning of the terms. *Id.* at 2, 5. Fennec maintains that it simply seeks to amend to bring its constructions in line with the patentee’s lexicography as it must under Federal Circuit precedent. *Id.* at 1-6. “Fennec could not offer to the Court in good faith a construction that differs from the patent’s lexicography, even if that plain and ordinary meaning is consistent with the patent’s lexicography, and therefore sought to change its construction to match the patent.” *Id.* at 5.

The Court finds that Fennec has met its burden of establishing good cause. There is a valid and important reason for Fennec’s amendment, *i.e.*, to substitute the patent’s own definition of the term “sodium thiosulfate” in accordance with the law. Where a patentee provides an express definition for a term in the patent itself, that definition governs the construction of the term. *See, e.g., Martek Bioscisc. Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1380 (Fed. Cir. 2009) (“When a patentee explicitly defines a claim term in the patent specification, the patentee’s definition controls.”); *see also Phillips*, 415 F.3d at 1316. Fennec discovered this requirement, and that its originally proposed construction did not comply, while preparing its *Markman* briefing. Fennec immediately notified Cipla of the need to amend to bring the constructions in line with the law. Cipla received Fennec’s proposed amendments only approximately a month after the JCCS was filed.

Cipla argues that Fennec cannot establish good cause for the amendment because it could have discovered its need to amend its proposed constructions of “sodium thiosulfate” sooner, or

used the explicit definition in the '793 patent from the outset, dispensing with the need to amend. Def. Brief in Opp'n., D.E. 101, at 6. Motions to amend patent documents are treated more stringently than motions to amend under Federal Rule of Civil Procedure 15. Local Patent Rule 3.7 requires a showing of both good cause and diligence to prevent the “shifting sands” approach to claim construction. *O2 Micro*, 467 F.2d at 1364. But this approach is not inflexible. Instead, Rule 3.7 seeks to balance a party’s need to develop its case and discover new information with the need to crystalize the legal theories in the case. *Janssen Pharms., Inc. v. Sandoz, Inc.*, No. 11-7247, 2013 WL 7901841, at *2 (D.N.J. May 22, 2013). For this reason, “Patent Rule 3.7 is not a straitjacket into which litigants are locked.” *TFH Publications, Inc. v. Doskocil Mfg. Co., Inc.*, 705 F.Supp.2d 361, 366 (D.N.J.2010). The Local Patent Rules and applicable case law do not require perfect diligence. Especially during early stages of litigation where parties are afforded a certain amount of reasonable flexibility. See *Helsinn Healthcare S.A. v. Dr. Reddy's Laboratories Ltd.*, No. 11-3962, 2013 WL 3336859, at *4 (D.N.J. July 2, 2013) (because the moving party was “conscientiously pursuing its obligations,” the court granted its motion to amend its invalidity contentions despite the moving party not having acted “as expeditiously as possible”).

Cipla is correct that Fennec could have been more diligent in discovering its need to amend sooner. Fennec concedes that it failed to appreciate that the patent’s lexicography controls and that an amendment to the JCCS would therefore be necessary until it was drafting its *Markman* brief. But mistake or inadvertence do not necessarily negate or preclude a finding of good cause amend a patent document under Rule 3.7. See *TFH Publ’ns, Inc.*, 705 F. Supp. 2d at 363 (allowing plaintiff to amend its disclosure of asserted claims where it had omitted several claims “through simple inadvertence and oversight”); *Int’l Development, LLC v. Simon Nicholas*

Richmond and Adventive Ideas, LLC, No. 09-2495, 2010 WL 3946714, at *1 (D.N.J. Oct. 4, 2010) (finding good cause for defendants to amend their infringement contentions six months after serving them where they inadvertently omitted certain products covered by the patent and defense counsel was not “previously aware of these omissions because he had ‘no prior occasion to revisit [them]’”); *Janssen Pharms., Inc. v. Sandoz, Inc.*, No. 11-7247, 2012 WL 12903176, * 4 (D.N.J. Oct. 25, 2012) (finding plaintiffs established good cause to permit the amendment where they forgot to include a particular claim in their asserted claims by mistake, only realized the mistake when preparing their infringement contentions, but then diligently sought to correct their mistake). While the Court acknowledges Fennec could have been more diligent in discovering the patent’s lexicography governs the construction for “sodium thiosulfate,” perfect diligence is not required under Rule 3.7. *See Eisai R & D Mgmt. Co. v. Shilpa Medicare Ltd.*, 656 F. Supp. 3d 515, 525 (D.N.J. 2023) (“good cause ‘does not require perfect diligence’”); *AS America, Inc. v. Masco Corp. of Indiana*, No. 13-05, 2013 WL 4084237, at *2-3 (D.N.J. Aug. 13, 2013) (granting defendant’s motion to amend invalidity contentions “even in the absence of perfect diligence”).

Fennec’s proposed amendment does not undermine the purpose behind Rule 3.7. There is no evidence that Fennec is engaging in gamesmanship or seeks to gain an unfair strategic advantage. *See Eisai R & D Mgmt. Co.*, 656 F. Supp. 3d at 525 (finding that defendants’ proposed amendments to their invalidity contentions were not motivated by gamesmanship but instead by the introduction of a new patent). Instead, Fennec seeks to conform its “sodium thiosulfate” construction to the inventor’s lexicography in accordance with Federal Circuit precedent.

Furthermore, in light of the recent addition of the related '018 patent to this litigation, it would be a waste of judicial resources to deny Fennec the opportunity to amend its construction for “sodium thiosulfate” in the '793 patent. *See Amgen Inc. v. Kashiv Biosciences, LLC*, No. 18-3347, 2019 WL 5445974, at *3 (D.N.J. Oct. 24, 2019) (finding “it would be a waste of judicial resources to push forward with claim construction as it has been submitted . . . knowing well that it contains what one side claims is an error). In the absence of the amendment, claim construction for the District Court would be particularly complex and unwieldy. Judge Semper likely would be faced with two different proposed constructions for “sodium thiosulfate,” both from Fennec. That is, Fennec’s original proposed construction for “sodium thiosulfate” for the '793 patent and the inventor’s lexicography for “sodium thiosulfate” for the '018 patent. Thus, the Court finds allowing the amendment particularly prudent in light of the fact that the '018 patent was recently added to the case. In light of these unusual circumstances, the Court is compelled to find good cause for the amendment to the JCCS.

c. Unfair Prejudice

Having determined that Fennec has demonstrated timeliness and good cause for the amendment, the Court now must decide whether the proposed amendment will unfairly prejudice Cipla. This analysis requires the Court to consider whether allowing the proposed amendments would require Cipla to expend additional significant resources or unduly delay resolution of this matter. *See TFH Publ’ns, Inc.*, 705 F. Supp. 2d at 366. The Court finds that the amendment will cause Cipla to suffer no appreciable prejudice.

First, allowing Fennec’s proposed amendment will not significantly delay the resolution of this matter. Fact discovery is not scheduled to close until November 2024. Expert discovery will not close until April 2025. A *Markman* hearing has not yet been scheduled. *Markman*

briefing was halted as soon as the parties raised this dispute. Although claim construction will take place soon after this motion is decided and *Markman* briefing is complete, this case is still relatively early in the litigation process, and dispositive motion practice and trial are not imminent. *See Janssen Pharms., Inc. v. Pharmascience, Inc.*, No. 19-21590, 2021 WL 2593337, at *3 (D.N.J. June 24, 2021) (allowing amendment “[d]espite its age, [since] the case is not near motion practice or a trial”).

Cipla also contends that permitting Fennec to amend now would require Cipla to expend significant resources in formulating new positions to address and respond to Fennec’s new constructions. But Cipla does not explain what those additional resource expenditures would be. Cipla does not contend that it will require additional discovery because of the proposed amendment. And although the amendment might require Cipla to revise its approach to *Markman*, there is no reason to believe that it will require entire re-briefing under new theories, because *Markman* briefing was not complete when Fennec raised the prospect of the amendment. Moreover, Cipla surely has been aware of, and prepared to account for, the definitions of the relevant terms in the ’793 patent. In short, Cipla does not explain, and the Court cannot independently identify, any significant additional expense that Cipla will bear if the Court allows the amendment. Further, courts have found no undue prejudice where parties have incurred additional expenses in responding to amended patent documents. *See TFH Publ’ns, Inc.*, 705 F. Supp. 2d at 366-67 (permitting amendment despite defendant incurring “additional legal expenses” to review its contentions); *see also AS Am., Inc.*, 2013 WL 4084237, at *3 (“Although defendant’s amendment may require some additional work on plaintiff’s part, the additional work is not significant or vexatious.”); *Abraxis BioScience, LLC*, 2017 WL 2079647, at *4 (“The fact that some additional work may be required does not constitute undue prejudice”). Finally, the

Court can accommodate any modest request for additional time for *Markman* briefing and to extend the close of fact and expert discovery. Accordingly, while there might be some prejudice to Cipla in having to reframe their *Markman* briefs, the Court does not find that it rises to the level of undue burden.

Even if Fennec had not filed the motion to amend, Fennec and Cipla would have had to amend the JCCS, revise their *Markman* briefing, and seek additional time to do so, in light of the recent addition of the '018 patent. As noted above, while this motion was under consideration, the parties agreed to permit Fennec to amend its second Amended Complaint to add the newly issued '018 patent. The definition for “sodium thiosulfate” in the '018 patent mirrors the definition for the term in the '793 patent. Thus, the parties will be filing an amended JCCS to include proposed constructions for the '018 patent. Although Cipla complains it will suffer prejudice by having to formulate responses to Fennec’s amended constructions for the term “sodium thiosulfate” for the '793 patent, it would have to do so in any event for the '018 patent. To hold otherwise would foist on the District Court a set of *Markman* terms for which Fennec proposes two different constructions for the term “sodium thiosulfate.” Moreover, the District Court would be faced with the patentee lexicography for the '018 patent, and the plain and ordinary meaning of the term for the '793 patent. That illogical result far surpasses any potential prejudice that Cipla might suffer from the amendment.

Accordingly, the Court finds it appropriate to permit Fennec to amend the JCCS. The Court also denies Cipla’s request for the imposition of attorney’s fees and costs pursuant to

Federal Rule of Civil Procedure 16(f) due to Fennec's failure to comply with scheduling orders and associated delays in this action.⁴

IV. CONCLUSION

For the reasons stated herein, Fennec's motion to amend the JCCS is granted. An Order consistent with this Opinion will issue.

s/ Michael A. Hammer
UNITED STATES MAGISTRATE JUDGE

Dated: October 7, 2024

⁴ Rule 16(f)(1)(C) authorizes a court to impose sanctions on a party that has failed "to obey a scheduling or other pretrial order." The Court finds it appropriate to deny Cipla's request for the imposition of sanctions for several reasons. First, Cipla fails to point to any order Fennec has violated. Indeed, the parties themselves entered into, and the Court granted, two stipulations to extend the deadlines for *Markman* briefing in an effort for the parties to try to informally resolve this dispute. Second, although Cipla contends that Fennec should be sanctioned because it waited until three days before *Markman* briefing was due to seek to amend its construction of the sodium thiosulfate terms, the Court interprets the record differently. The parties' papers reflect an amicable and collaborative approach by the Fennec and Cipla parties in this matter. *See, e.g.*, Def. Brief in Opp'n., D.E. 101, at 2 ("[l]eading up to the submission of the JCCS, the parties had three exchanges and agreed to four extensions of claim construction deadlines"); Reply, D.E. 102, at 6 ("As Cipla's brief describes, throughout this litigation, *both* parties have been liberal in requesting and agreeing to changes in the schedule, all of which the Court has summarily granted." (emphasis in original)). The Court will not now sanction a party for taking its meet-and-confer obligations seriously. Third, monetary sanctions are intended to compensate for fees expended due to alleged misconduct. *See Engage Healthcare Commc'ns, LLC v. Intellisphere, LLC*, No. 12-787, 2019 WL 7640295, at *12 (D.N.J. Jan. 23, 2019) (in determining that defendant failed to show harm due to alleged discovery violation, the court noted "[monetary] sanctions are intended to compensate, not punish"). Here, the Court finds no misconduct nor any reason to compensate Cipla for its attorney's fees.